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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/114,973	07/14/1998	WILLIAM F. DOVE	960296.95491	9862

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QUARLES & BRADY LLP  
FIRSTAR PLAZA, ONE SOUTH PINCKNEY STREET  
P.O. BOX 2113 SUITE 600  
MADISON, WI 53701-2113

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**Application No.  
**09/114,973**Applicant(s)  
**Dove et al.**Examiner  
**Joseph Weitach**Art Unit  
**1632**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Nov 25, 2002
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 4-31, and 34-42 is/are allowed.
- 6) ☒ Claim(s) 3, 32, and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_                      6) ☐ Other:

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### **DETAILED ACTION**

This application filed July 14, 1998, is a continuation in part of application of 08/751,292, filed November 18, 1996, now US Patent 5,780,236.

Applicant's amendment filed December 2, 2002, paper number 29, has been received and entered. Claims 1, 7, 23, 25-28, 30, 36 and 40 have been amended. Claims 1-42 are pending and currently under examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 32 and 33 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Initially it is noted that claim amendments and applicant's arguments have obviated the each of the specific basis of rejection previously set forth for claims 1, 2, 4-31, 34-42. See Applicant's amendment, bridging pages 12-14.

With respect to claims 3 and 32 (and dependent claim 33) Applicants maintain as set forth in the specification that the skilled artisan understands the term and that it can only be determined by a case-by-case basis. By example, Applicants note that in some cases a level

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below the tenth percentile or above the ninetieth percentile could be extreme, whereas in another case, extreme levels might be established at the second and 98<sup>th</sup> percentiles. See Applicant's amendment, bridging pages 12-13. Applicant's arguments have been fully considered, but not found persuasive.

As noted in Applicant's arguments, the term 'extreme' encompasses many degrees of variation which is subject to change under various circumstances. The specification does not specifically describe the metes and bounds of the term, nor does it describe how the artisan would determine the metes and bounds of the term on a case-by-case basis. Therefore, the term and claim is indefinite because what one artisan would consider extreme in one case, may not be considered extreme by a second artisan.

### ***Conclusion***

Claims 1, 2, 4-31, 34-42 are allowed. As noted in the previous office action the claims are free of the art of record because while cross-breeding for the analysis of a loci has been described in the art the art fails to teach the specific methodology instantly claimed. Further, the art fails to anticipate or make obvious the specific non-human animals made by the methods, in particular the non-human animals with specific genetic backgrounds comprising specific point mutations and various phenotype combinations would not have been generated with the cross-breeding methods previously described in the art.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

*Deborah Crouch*

DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1800/630